

FROM W&C LLP 19TH FL

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REMARKS

I. Restriction Requirement

Claims 1-16 are pending. It is alleged that the subject application contains the following inventions or groups of inventions which are independent and patentably distinct:

Group I – claims 1, 10, 11 and 14 drawn to a film coating composition;

Group II claims 2 and 15 drawn to a film coat covering a pharmaceutical core;

Group III – claims 3 and 5-9 drawn to a pharmaceutical formulation;

Group IV -- claims 4 and 5-9 drawn to a pharmaceutical formulation comprising a plurality of beads;

Group V – claims 3, 12 and 16 drawn to a process for preparing a pharmaceutical formulation comprising a dispersion; and

Group VI - claims 4 and 13 drawn to process for preparing a pharmaceutical formulation comprising coating each bead with a film coating composition wherein the composition comprises a dispersion.

With traverse, Applicant elects the invention of Group III for examination purposes.

II. Traversal of the Requirement

The recitation of each and every one of claims 1-16 is characterized by the following combination of ingredients:

- (a) an ethyl acrylate/methyl methacrylate copolymer
- (b) an anti-sticking agent which is glyceryl monostearate ("GMS"); and
- (c) a surface agent, wherein the surface active agent is present in a low amount, e.g., less than 1.3% by weight of the dispersion (claim 1, 10, 11, 14) and less than 5.1% by weight of the film coat. (claims 2-9, 12, 13, 15 and 16).

This combination of ingredients (a), (b) and (c) is the special technical feature running throughout and linking the claims. As set forth in the detailed description of the invention at paragraph [0022] of the published patent application US-2005-2387719-A1, the present invention features a pharmaceutical composition which surprisingly has a low amount of surface active agent, i.e., ingredient (c). Unexpectedly, as evidence by the Examples, the claimed

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invention is characterized by a stable release profile following storage. In this regard, the Examiner's attention is directed to paragraph [0054] of the published patent application where it is reported that "[i]t was surprisingly found that the film coating of the present invention could be made with low amounts of surface active agents and that such a coating exhibited stability over time."

The basis for the restriction is that there is no special technical feature shared by the claims which distinguishes the claimed invention over the prior art. In this regard, the Examiner relies on a publication disclosed by Applicant in an Information Disclosure Statement filed 31 January 2005 with the application, i.e., Petereit et al., European Journal of Pharmaceutics and Biopharmaceutics, vol. 41, no. 4, August 1, 1995, pages 219-228 ("Petereit"). Specifically, the Examiner states that Petereit shows that formulations comprising an ethyl acrylate/methyl methacrylate copolymer and GMS are known.

It appears, however, that the Examiner has overlooked ingredient (c) and the fact that the claimed combination of ingredients (a), (b) and (c) provides a pharmaceutical composition which surprisingly has a low amount of a surface active agent (See [0022] and [0054] of the published patent application, and the Examples). And it is this combination of ingredients which distinguishes the claimed invention over the prior art. Since all of the pending claims share this special technical feature, there is unity of invention and the restriction requirement should be withdrawn.

III. The Restriction Requirement Violates 37 C.F.R. §1.475

The controlling regulation, 37 C.F.R. §1.475, provides that the requirement of unity of invention shall be fulfilled when there is a technical relationship among the claims involving one or more special technical features that "define a contribution" over the prior art.

§1.475 Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.

- (a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled

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only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. (Emphasis added)

All of the pending claims 1-16 recite the combination of ingredients (a), (b) and (c). Applicant submits that one must look at the entirety of the claims and cooperation of the recited ingredients to properly determine whether there is a special technical feature that defines a contribution over the prior art. Dissecting a claim into its recited features as the Examiner has done on page 2 of the Office action, i.e., ingredients (a) and (b) are known in the prior art, reduces a claim into a combination of old parts without any consideration of the contribution which the sum of the parts defines over the prior art. The cited document Petereit validates the Examiner's position that formulations comprising an ethyl acrylate/methyl methacrylate and GMS are known in the prior art. However, that same document validates Applicant's position that the claimed combination of ingredients (a), (b) and (c) is new and defines a contribution which each of claims 1-16 makes over the prior art. Therefore, the restriction requirement is patently improper.

With specific regard to Groups III and IV, the restriction of these two groups makes no sense in view of the fact that the composition of the formulation of Groups III and IV is identical. Patentability does not reside with the shape or form of the formulation but rather with the composition of the formulation. It is expected that the prior art search and examination would be the same for both Groups III and IV. Furthermore, 37 C.F.R. §1.475(b)(1) expressly provides that there is unity of invention with respect to claims drawn to a product and a process for making that product. Groups III and V and Groups IV and VI are related as product and process. Therefore, pursuant to 37 C.F.R. §1.475(b)(1), there is at least unity of invention between Groups III and V and Groups IV and VI, respectively.

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CONCLUSION

Applicants respectfully submit that the restriction requirement is flawed and contravenes 37 C.F.R. §1.475.. Applicant requests withdrawal of the restriction requirement, and rejoinder and examination of all of the pending claims 1-16 in this application

Any fees due in connection with this response should be charged to Deposit Account No. 23-1703.

Dated: 24 October 2006

Respectfully submitted,



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